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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/596,001	06/16/00	BIEDERMANN	E 69176

022242
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HM12/1101

EXAMINER	
TRUONG, T	
ART UNIT	**PAPER NUMBER**
1624	10

DATE MAILED: 11/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/596,001	BIEDERMANN ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election of species containing G1 in paper #9 is acknowledged.

Claims 1-31 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The phrase "such as" (in the definitions of variables) renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

b. The phrase "partially hydrated" (in describing cycles) is not an appropriate term because "hydrate" means water not hydrogen. Perhaps applicant means "hydrogenated".

c. Claims 5 and 6 lack antecedent basis. Said claims depend on claim 4, but recite "alkenylene" for A which is not recited in claim 4.

d. The term "diensaureamide" is not an English chemical term. Applicant is requested to use appropriate translated term.

e. Claim 8 is an improper multiple dependent claim because it refers back to species claim 7, and also refers back to formula (I) and claim 1 at the same time.

f. Claims 11, 13, 24, and 31 are also improper multiple dependent claims as they refer to two claims at the same time, and not in the alternative language.

g. The term "suitable nucleofuge" is not an art-recognized term.

h. The term "residue" is not clear what part of the functional group is intended.

i. The phrase "according to method variant" renders claim 8 an omnibus type claim because one cannot tell what is included or excluded from said claim.

j. Claims 9-11, and ~~13~~ 31 provide for the use of compounds in claim 7, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9-11, and ~~13~~ 31 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

k. Claim 24 recites the broad recitation "0.01 to 2.0mg", and the claim also recites "0.1, 1, 2...mg" which is the narrower statement of the range/limitation. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Scope of Enablement:** Claims 1, and 9-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of solid tumors of

colon, lung, and leukemia, does not reasonably provide enablement for the treatment of other cancers (particularly metastases), nor does it provide enablement for transdermal, inhalation, buccal, otological, and ophthalmalogical compositions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The enablement for treating proliferative diseases, cancers and metastasized cancers is not found in the instant disclosure. A showing of the inhibition of solid tumor growth does not sufficiently guide the skilled oncologist to treat various metastasized cancers and proliferative diseases in general. The treatment of solid tumor growth cannot be extrapolated to the treatment of soft tumor growth or malignant tumor growth. There has never been a compound capable of treating cancer generally, let alone treating metastasized cancers. Once a cancer has metastasized, the disease is at its terminal phase, to which no treatment can prevail. Furthermore, different types of cancers affect different organs and have different modes of growth and harm to the body as well as different vulnerabilities. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. Therefore, it is beyond the skill of oncologists today to get an agent to be effective against cancers or metastasized cancers in general.

Also, there has never been a chemotherapy agent that is delivered transdermally, intranasally, or by ways other than oral and intravenous. The specification does not provide data for bioavailability or efficacy of these unconventional means of delivering chemotherapy agents.

Thus, it would require undue experimentation for one skilled in the art to formulate such unconventional compositions.

When the best efforts have failed to achieve a goal, it is reasonable for the PTO to require evidence that such a goal has been accomplished, ***In re Ferens***, 163 USPQ 609. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal requires undue experimentation, ***Genetech vs. Novo Nordisk***, 42 USPQ 2nd 1001, 1006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by the following references:

a. **Nishikawa et. al.** (J. Med. Chem., 1989, Vol. 32, pp. 583-593): Compounds #18a, 18b on page 585 are embraced by the instant formula I with the following substituents:

i. Both A and D represent alkylene;

ii. k is 0; r is 0 while s is 1;

iii. Both R^{13} and R^{15} are phenyl;

The process claim 8 is also taught in the last paragraph of the left column on page 585. The use in claim 9 is also embraced because the disclosed compounds inhibit 5-lipoxygenase.

b. **Nishikawa et. al.** (EP 210,782) : Compounds listed in Table 5 (e.g., compounds #7, 11, and 22), their preparation and use are embraced by the instant claims 1-3, 8 and 9.

c. **Haeck et. al.** (EP 048,045): Compound #1 on line 21 of page 11 is embraced by the instant formula I with the following substituents:

iv. Both A and D represent alkylene;

v. k, r and s all have a value of 0;

vi. R^{13} is phenyl substituted with trifluoromethyl.

The process claim 8 is taught in Example IV on page 11. The use in claim 9 is also embraced because the disclosed compound has antiagressive and analgesic activity.

Thus, at the time of the invention, one skilled in the art would have known how to make and use compounds of formula I with substituents discussed above.

Information Disclosure Statement

The IDS filed on 1-3-01 has been considered except for two entries. The citation for "Allgemeine Pathologie and Pathologische Anatomie" needs author and date. The citation for Rote Liste needs author.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RICHARD L. RAYMOND
PRIMARY EXAMINER
ART UNIT 1624

T. Truong
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October 30, 2001